Title: NIAID PROTOCOL TEMPLATE GUIDANCE

APPROVAL

Approval Mechanism	***NIAID Executive Committee (EXCOM)***	***April 13, 2006***

1.0 PURPOSE

1.1. To provide a standardized template to assist NIAID investigators in writing and developing clinical research protocols that are in compliance with regulatory and other requirements.

2.0 BACKGROUND

2.1. This template was developed by a group of NIAID staff from all Divisions in an effort to facilitate protocol development for investigators. This trans-NIAID working group proposed that the use of a standard protocol template would result in greater efficiencies in protocol writing and review processes.

3.0 SCOPE

3.1 These templates will not supersede current templates already in use in existing Networks. However, new initiatives and new Networks will use these templates as a basis for developing protocol templates.

4.0 RESPONSIBILITIES

4.1 DCR personnel are responsible for ongoing evaluation of the template to assure that it meets current requirements for protocol submission.

4.2 Investigators are responsible for accessing relevant reference links and specific guidance for protocol submissions from individual Divisions.

5.0 PROTOCOL TEMPLATES WITH INSTRUCTIONS FOR USE BY EXTRAMURAL AND INTRAMURAL INVESTIGATORS ARE ATTACHED

6.0 REFERENCES/LINKS

6.1. Supercedes: None

6.2. The below online information is current as of the Effective Date of this policy:

Guidance for Industry E 6 Good Clinical Practice: Consolidated Guidance
www.cc.nih.gov/ccc/clinicalresearch/guidance.pdf

7.0 INQUIRIES/CONTACT INFORMATION

7.1. For questions or comments please contact NCRSexecsec@niaid.nih.gov.

8.0 AVAILABILITY

8.1. This guidance and the sample protocol templates are available on the DCR website. Hardcopy documents are filed in the DCR office.

9.0 ATTACHMENTS

9.1. Attachment A. Protocol Template and Instructions for Extramural Investigators

Attachment B. Protocol Template and Instructions for Intramural Investigators

9.2 Attachment C. List of Protocol Development Committee members

10.0 REVIEW SCHEDULE/CHANGE SUMMARY

10.1 The change summary table below will be updated when this guidance is revised.

Protocol Template Guidance Document Version #	Date	Replaces	Date of Revision	Rationale for Revision/Retirement

10.2 The protocol templates will be evaluated in an ongoing manner based on feedback from investigators and other users, and in conjunction with direction from regulatory and review staff. The templates will be reviewed and evaluated every 6 months in order to assure that they meet current regulatory requirements.

EXTRAMURAL Version #	Date	Replaces	Date of Revision	Rationale for /Revision/Retirement
INTRAMURAL Version #	Date	Replaces	Date of Revision	Rationale for /Revision/Retirement